K083141

SIMPACT

NOV - 7 2008

Special 510(k) Summary of Safety and Effectiveness: SIMPACT Implant System

Submitter:	SIMPACT LLC 300 Interpace Parkway Suite 410 Parsippany, NJ 07054
Contact Person	Mark Schenk Manager QA/RA Phone: 973-588-8932 Email: mschenk@simpactdental.com
Date Prepared	October 21, 2008

Currently Legally Marketed Device Information	
Trade Name	SIMPACT Endosseous Dental Implant System
Common Name	Dental Abutments
Classification Name and Number	Endosseous dental implant and abutment 21 CFR 872.3630 21 CFR 872.3640
Product Code	DZE, NHA
Predicate Devices	SIMPACT K081226
Device Description	The SIMPACT Endosseous Dental Implant System, Line Extension
Intended Use	Simpact Dental Implant System is intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained terminal or intermediate abutment support for fixed bridgework. The Simpact implant is a threaded/tapered internal connection implant. The Simpact implant is intended for immediate placement, where immediate implant placement is defined by the International Congress of Oral Implantologists (ICOI) as the placement of an implant at the time of tooth extraction, into the extraction socket. The Simpact implant is intended for immediate provisional loading when primary stability and proper occlusion are present. Immediate Provisionalization is defined by the International Congress of Oral Implantologists (ICOI) as a clinical protocol for the placement of an interim prosthesis with occlusal contact with the opposing dentition, at the same clinical visit of implant placement. The Simpact implant can be restored with a temporary prosthesis in single tooth and multiple tooth applications.

Statement of Technological Comparison	The SIMPACT Implant System Line Extensions and the SIMPACT Implant System (K081226) have the same indications for use and are made of the same materials. The only dimensional specification changes were made to the design.
Conclusion	The SIMPACT Implant System Line Extensions are substantially equivalent to itself. This conclusion is based upon the fact that this device is substantially equivalent in terms of the intended use, the indications for use, materials, design and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Mark Schenk
Manager of Quality Assurance/ Regulatory Affairs
Simpact LLC
300 Interpace Parkway, Suite 410
Parsippany, New Jersey 07054

Re: K083141
Trade/Device Name: SIMPACT Endosseous Dental Implant
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: NHA
Dated: October 22, 2008
Received: October 23, 2008

Dear Mr. Schenk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Diane G. Richardson MD

Chiu S. Lin, Ph. D FOR DR. CHIU LIN
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number K081226

Device Name: SIMPACT Endosseous Dental Implant

Indications for Use:

Simpact Dental Implant System is intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained terminal or intermediate abutment support for fixed bridgework.

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Prescription Use X **AND/OR Over-the-counter** _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083741